

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

AMERICANS FOR BENEFICIARY CHOICE,
et al.

Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Civil Action No. 4:24-CV-439-O

COUNCIL FOR MEDICARE CHOICE, et al.

Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Civil Action No. 4:24-CV-446-O

**DEFENDANTS' UNOPPOSED MOTION FOR LEAVE
TO FILE SUPPLEMENTAL AUTHORITY**

The government respectfully moves, under local rule 56.7, for leave to file notice of a recent case from the Supreme Court, *FDA v. Wages & White Lion Investments, LLC*, -- U.S. ----, 2025 WL 978101 (Apr. 2, 2025) (slip opinion included with the attached proposed notice, and cited as “Slip Op.”), vacating a decision of the *en banc* Fifth Circuit on which Plaintiff ABC relied (*see* ABC Br. at 21, 27, 28–29 (ECF 51¹); ABC Reply at 18, 20 (ECF 55)). Plaintiffs do

¹ ECF cites are to the docket of the relevant case as indicated, i.e., either the ABC case or the CMC case.

not oppose this request, and the government does not oppose Plaintiffs' filing of a response to the notice.

In *Wages & White Lion*, certain e-cigarette companies argued that the FDA's denial of their applications to sell e-cigarettes were arbitrary and capricious in large part because the FDA had allegedly changed, without adequate explanation, the requirements the companies needed to meet for regulatory approval. (Slip Op. at 22.) The Supreme Court unanimously disagreed, holding that the FDA's regulatory denials "were sufficiently consistent with its predecisional guidance" so that the companies could not show that FDA had in fact changed its position at all (*id.* at 25) and that to the extent there was any change, the agency adequately explained its rationale (*id.* at 39–40). In doing so, the Supreme Court elucidated the relevant legal standard lower courts should apply to arbitrary-and-capricious arguments, and the government respectfully explains below why the case supports the government's contention that Plaintiffs' change-in-position argument, reliance argument, and fair-notice argument in this case all fail.

First, the Supreme Court's discussion shows why CMS did not, as Plaintiffs argue, change its interpretation of the Medicare statute without acknowledging and explaining the change. Plaintiffs argue that the mere fact that CMS regulated administrative payments separately from other compensation must mean that CMS interpreted the statutory term "compensation" at 42 U.S.C. § 1395w-21(j)(2)(D) to exclude administrative payments. Thus, even though the Final Rule acknowledged and explained why CMS was changing its *regulatory* treatment of administrative payments, Plaintiffs fault the agency for not acknowledging and explaining what they claim was an accompanying change in *statutory* interpretation. (See CMC Br. at 21 (ECF 51); ABC Br. at 28–29 (ECF 51); *see also* Stay Order at 9.)

That kind of change-in-implicit-position theory does not survive *Wages & White Lion*, in

which the Supreme Court held that “noncommittal” agency statements about what legal standard it would apply fall short of the kind of “hard-and-fast commitment” to a particular legal position that triggers change-in-position jurisprudence. (Slip Op. at 27.) And here, the record lacks even “noncommittal” statements about the meaning of the statutory term “compensation,” and nothing like the “hard-and-fast commitment” to a legal position the Supreme Court has now clarified that change-in-position arguments require.

Second, the Supreme Court emphasized the low bar an agency faces under arbitrary-and-capricious review even when changing policies on which third parties rely. It reiterated that an agency that is changing policies “does not need to show that the reasons for the new policy are *better* than the reasons for the old one,” but must (among other things) simply “be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.” (Slip Op. at 24 (internal quotation marks and citations omitted).) This undercuts ABC’s argument, based on a statement in the now-vacated Fifth Circuit decision, that agencies “*must* provide a ‘detailed justification’ for why they are changing policies whenever reliance interests are at stake. (ABC Br. at 21 (quoting *Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357, 381 (5th Cir. 2024) (en banc)). Rather, the APA simply requires that the agency be “cognizant” of reliance interests (Slip Op. at 24)—a burden that was met here, as evidenced by, among other things, the fact that CMS’s Final Rule *tripled* the original proposed compensation amount in response to the industry’s reliance arguments received during the comment period. The APA requires no more.

Finally, the Supreme Court’s decision undercuts CMC’s fair-notice argument, which asserts that the Due Process Clause prohibits working out through individual adjudications which contract clauses violate the statutory requirement that the use of compensation “creates

incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs,” 42 U.S.C. § 1395w-21(j)(2)(D), and instead requires enumerating prohibited contract clauses up front through prospective rulemaking. (CMC Br. at 36–38 (ECF 51); *see also* Stay Order at 10.) That theory mirrors the e-cigarette companies’ contention in *Wages & White Lion* that the FDA needed to announce in advance how it would evaluate whether any new e-cigarette “presents less risk than other tobacco products” under the relevant law. (Slip Op. at 11, 33 (quoting 21 U.S.C. § 387j(b)(1)(A) (Supreme Court’s emphasis removed).) In rejecting the claim, the Supreme Court reiterated the longstanding rule that “agencies are generally free to develop regulatory standards ‘either by general [legislative] rule or by individual order’ in an adjudication.” (Slip Op. at 19 (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 202–03 (1947)).) Thus, the FDA was not required to “perfectly predict the comparative-efficacy standard [it] ultimately applied to applications” in advance, because the law did not “impose[] an affirmative obligation on the FDA to spell out in detail how it expected” to do so. (Slip Op. at 36.) The Supreme Court also rejected the e-cigarette companies’ reliance on *Fox Television*—CMC’s main fair-notice case (CMC Br. at 36 (ECF 51))—because *Fox Television* dealt with a situation where “an agency changed position by ‘expanding the scope of its enforcement activity’” without previously stating that it would. (Slip Op. at 38 (quoting 556 U.S. at 517).) As the government has pointed out (Gov’t Br. at 43), CMC identifies no after-the-fact change in CMS’s policy during an adjudication. Thus, just as the FDA could “work out the meaning of the [Tobacco Control Act’s] comparative standard when evaluating” particular e-cigarette applications, CMS may “work out the meaning of” § 1395w-21(j)(2)(D)’s perverse-incentive standard when evaluating particular Medicare Advantage

contracts.² (Slip Op. at 37.)

Respectfully submitted,

CHAD E. MEACHAM
ACTING UNITED STATES ATTORNEY

/s/ Brian W. Stoltz
Brian W. Stoltz
Assistant United States Attorney
Texas Bar No. 24060668
1100 Commerce Street, Third Floor
Dallas, Texas 75242-1699
Telephone: 214-659-8626
Facsimile: 214-659-8807
brian.stoltz@usdoj.gov

Attorneys for Defendants

Certificate of Conference

I have conferred with Plaintiffs about the relief requested herein and it is unopposed.

/s/ Brian W. Stoltz
Brian W. Stoltz
Assistant United States Attorney

² To be sure, the Supreme Court evaluated the e-cigarette companies' argument in *Wages & White Lion* under its change-in-position doctrine and not the fair-notice standards of the Due Process Clause. (Slip Op. at 22, 36–37.) But it acknowledged that the e-cigarette companies' argument was “rooted in part on the constitutional right to due process” including concepts of “‘fair notice’” (*id.* at 22)—indeed, the fair-notice doctrine was one of the main rationales for the vacated Fifth Circuit decision, *see Wages & White Lion*, 90 F.4th at 374–76 (vacated decision's analysis of the fair-notice requirement). And the fact that the Supreme Court ultimately found it unnecessary to address the fair-notice argument separately, because “[i]t is unclear what, if any daylight exists between that conception of ‘fair notice’ and our change-in-position doctrine” (Slip Op. at 23), further buttresses the notion that the analysis in *Wages and White Lion* applies with equal force to CMC's fair-notice argument here.

Certificate of Service

On April 21, 2025, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Brian W. Stoltz
Brian W. Stoltz
Assistant United States Attorney